K 000207

FEB 4 2000

510(k) Summary

Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
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Trade Name:

Porocoat® Prodigy™ Hip Prosthesis

Common Name:

Total Hip Joint Replacement Prosthesis with porous coating

Classification:

Class II Device per 21 CFR 888.3358:
Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

Device Product Code:

Code: **87LPH** Prosthesis Hip Semi-constrained, Metal/Polymer, Cemented
No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

Substantially Equivalent Device:

Porocoat® Prodigy™ Hip Prosthesis **K931641**
Vision AML® Hip Prosthesis **K953694**

Device Descriptions:

The hip stem is manufactured from ASTM F-75 Cobalt-Chromium-Molybdenum alloy and has a sintered cobalt-chrome-molybdenum alloy bead porous coating (Porocoat®) applied to the stem. The porous coating is applied to the entire stem with the exception of the tapered stem tip region of all stems and a modified geometric cut-out area on the medial aspect of the mid portion of the stem of larger-sized prostheses. The stem is designed to be used with AML reamers and broaches and now has been modified to be used with the Excel®/AML impactor.

The design utilizes an anteverted neck with a taper for attachment of femoral ball heads. Cobalt-chromium-molybdenum alloy and aluminum ceramic femoral ball heads are intended to be used with the Prodigy Hip prosthesis to provide the femoral prosthetic articular surface for the total hip arthroplasty in combination with a porous coated

metal backed acetabular cup prosthesis that uses an ultra high molecular weight polyethylene bearing (UHMWPe) surface.

Intended use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for use:

Total hip replacement is indicated in the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic facture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Substantial equivalence:

The fundamental scientific technologies of the Prodigy Hip Prosthesis have not changed from the FDA cleared Prodigy Hip Prosthesis system (K931641) and the Vision AML Hip System (K953694). The intended use and indications for use of the Prodigy Hip Prosthesis have not changed from the FDA cleared Prodigy Hip Prosthesis system (K931641). The Prodigy hip stem is manufactured from ASTM F-75 Cobalt Chromium Molybdenum alloy as are the Prodigy hip stem cleared in K931641 and the Vision AML Hip System (K953694). With the exception of the minor design modifications, the Prodigy hip stem is identical to the Prodigy hip stem device cleared in K931641.

Based on conformance with the design control procedures requirements as specified in 21 CFR 820.30, similarities of design, commonly used materials, identical sterilization processes, the same indications for use and intended use, DePuy believes that the Porocoat Prodigy Hip Prosthesis to be substantially equivalent to the FDA cleared Prodigy Hip Prosthesis system (K931641) and the Vision AML Hip System (K953694).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K000207
Trade Name: Porocoat® Prodigy™ Hip Prosthesis
Regulatory Class: II
Product Code: LPH
Dated: January 17, 2000
Received: January 24, 2000

Dear Ms. Arentz:

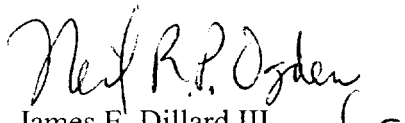
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000207

Device Name: Porocoat® Prodigy™ Hip Prosthesis

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Porocoat® Prodigy™ Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prostheses to the bone cement.

Concurrence of CDRH, Office of Device Evaluation

NPO for 3/20

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000207

Prescription Use 3/2 OR Over-The-Counter Use NB
(Per 21 CFR 801.109)